

510(k) Summary
per 21 CFR §807.92 (c)

AUG 12 2011

K112103

Submitter's Name and Address	Boston Scientific Corporation One Scimed Place Maple Grove, MN 55311
Contact Name and Information	Harlan Jones Regulatory Affairs Specialist II Tel: 763-255-0027 Fax: 763-494-2222 E-mail: Harlan.Jones@bsci.com
Date Prepared	July 14, 2011
Trade Name	Interlock™-35 Fibered IDC™ Occlusion System
Common Name	Vascular embolization device
Classification	Class II
Product Code	KRD, Vascular embolization devices (21 CFR 870.3300)
Predicate Device	Interlock-35 Fibered IDC Occlusion System (Vascular embolization device) K110295 SE: 3 Mar 2011
Reason for Submission	<p>The reason for this premarket notification is to seek clearance for a revision to the Directions for Use (DFU) for Boston Scientific Corporation's (BSC) Interlock™-35 Fibered IDC™ Occlusion System (Vascular embolization device). The device was previously cleared by FDA under K110295 as Interlock™-35 Fibered IDC™ Occlusion System (Vascular embolization device).</p> <p>Accordingly, BSC is submitting this Premarket Notification to incorporate results of non-clinical MRI testing in the DFU. The proposed DFU revisions are described in Section 4.2.1, <i>Proposed MRI Labeling</i>. The addition of MRI information is not prompted by field events or complaints; the additional information allows for safer and more effective use of the device. The revision has no effect on the Indications for Use, the Contraindications, or the device configuration. This Premarket Notification represents no other device or labeling changes</p>

Device Description

The Interlock-35 Fibered IDC Occlusion System includes a coil manufactured from a platinum-tungsten alloy that is mechanically attached to a coil delivery wire. This assembly is contained within an introducer sheath. The platinum coil contains synthetic fibers for greater thrombogenicity. The Interlock-35 Fibered IDC Occlusion System is designed to be delivered under fluoroscopy through a 5F (0.035 in [0.89 mm] or 0.038 in [0.97 mm] inner lumen) Diagnostic Catheter (e.g. Imager™ II Diagnostic Catheter). The interlocking delivery wire design allows the coil to be advanced and retracted before final placement in the vessel, thus aiding in more controlled delivery including the ability to withdraw the coil prior to deployment.

Indications for Use

The Interlock-35 Fibered IDC Occlusion System is indicated to obstruct or reduce rate of blood flow in the peripheral vasculature. This device is not intended for neurovascular use.

Non-Clinical Performance Data

Non-clinical testing demonstrates that the Interlock-35 Fibered IDC Occlusion System will not present additional risk to a patient during a MRI procedure in comparison to risks imposed by gravitational, and other normal daily activities, or a temperature rise that is experienced during a feverish condition. The results of testing conducted under methods described by ASTM F2182-02a, ASTM F2052-06e1, ASTM F2213-06 and ASTM F2119-07 have demonstrated that the Coils are MR Conditional and can be scanned safely under a static magnetic field of 1.5 Tesla or 3.0 Tesla.

Testing at field strengths other than 1.5 Tesla or 3.0 Tesla has not been performed to evaluate coil migration or heating.

Conclusion

The modifications do not affect the intended use or alter the fundamental scientific technology of the predicate Boston Scientific Interlock-35 Fibered IDC Occlusion System (K110295).

Based on the Indications for Use, unaltered technological characteristics, and submitted non-clinical performance data supporting this modification, the Boston Scientific Interlock-35 Fibered IDC Occlusion System is shown to be appropriate for its intended use and demonstrates that the device is as safe, as effective, and performs as well as the predicate device.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room - WO66-G609
Silver Spring, MD 20993-0002

Boston Scientific Corporation
c/o Mr. Harlan Jones
Regulatory Affairs Specialist II
One Scimed Place
Maple Grove, MN 55311

AUG 12 2011

Re: K112103

Trade/Device Name: Interlock™-35 Fibered IDC™ Occlusion System
Regulation Number: 21 CFR 870.3300
Regulation Name: Vascular Embolization Device
Regulatory Class: Class II
Product Code: KRD
Dated: July 21, 2011
Received: July 22, 2011

Dear Mr. Jones :

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

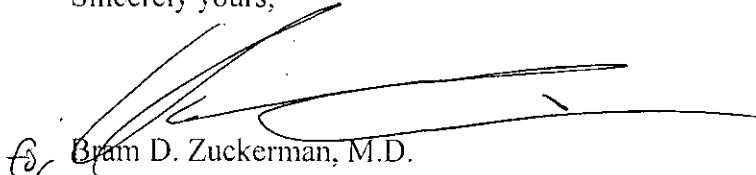
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device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,


Bram D. Zuckerman, M.D.
Director
Center for Devices and Radiological Health
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K112103

Device Name: Interlock-35™ Fibered IDC™ Occlusion System

Indications for Use:

The Interlock-35 Fibered IDC Occlusion System is indicated to obstruct or reduce rate of blood flow in the peripheral vasculature. This device is not intended for neurovascular use.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of Cardiovascular Devices

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